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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,470

07/31/2003

Robert Kincaid

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AGILENT TECHNOLOGIES INC.
INTELLECTUAL PROPERTY ADMINISTRATION,LEGAL DEPT.
MS BLDG. E P.O. BOX 7599
LOVELAND, CO 80537

EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

04/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No. 10/633,470	Applicant(s) KINCAID ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The applicants correctly noted on page 8, footnote 1 that the citation of Taylor was omitted in the first sentence of the rejection. Taylor was explicitly discussed in the rejection and was made of record in the Office action mailed 21 September 2006. The omission has been corrected in this Office action.
2. This Office action contains new grounds of rejection under 35 U.S.C. 103(a) necessitated by the amendment filed 30 January 2009.

Status of the Claims

3. Claims 1-7, and 9-14 are pending.
Claims 1-7, and 9-14 are rejected.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-6 and 9 under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. in view of Taylor in view of Nova et al. in the Office action mailed 30 October 2008 is withdrawn in view of the amendment to the claims filed 30 January 2009.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7, 9, 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (Nature Biotechnology Vol. 14, pages 1675-1680 (1996)) in view of Taylor (U.S. Patent Application Publication No. 2002/0052882 A1) in view of Nova et al. (U.S. Patent No. 6,017,496) in view of Ramdas et al. (BioTechniques Vol. 31, pages 546-552 (2001)).

The claims are drawn to a virtualizing microarray system comprising a microarray comprising a memory element that contains data of the microarray features and instructions that generate data of a subset of the data of the microarray features. In addition to the microarray the system comprises a processing component that processes a subset of the features of the microarray at a feature extraction step and further analyzes the data of the features. In some embodiments the virtual microarray comprises data concerning the position of the elements of the microarray, the type of probe in the microarray, the target molecule of the probe of the microarray, and the function, process, and cellular component of the element of the microarray. In some embodiments the virtual microarray is made by removing features of the microarray (termed masking in claim 6). In some embodiments the virtual microarray comprises data concerning molecules whose synthesis is directed by the molecule that binds to a probe in the microarray. In some embodiments the microarray contains a header and the instructions associate the header with features in the microarray. In some embodiments the virtual microarray is made by a scanner, a data processing system, or a visualization system.

Lockhart et al. shows at least in figure 1 that oligonucleotide arrays are useful for determining the levels of messenger RNA in samples applied to the arrays. Lockhart et al. shows isolation of messenger RNA from cytoplasm of cells on page 1679, and analysis of array data by scanning and computerized analysis on page 1679.

Lockhart et al. does not show microarrays comprising memory elements that comprise data of the microarray features, or details of microarray processing apparatus, or analysis of a subset of the microarray features, or explicitly a microarray scanner apparatus that processes microarrays.

Taylor shows a virtual microarray in page 1 in which correspondence between positions of a physical microarray and the virtual microarray are known. Taylor shows deletion of data from the microarray when creating the virtual microarray in page 2, paragraphs 28 and 29, and page 3 paragraph 34. Taylor shows virtual microarrays that comprise data related to DNA probe elements of the microarray on pages 6-9, including information about the probe, and the gene and tissue from which it was derived. on pages 6-9 Taylor shows that the data associated with the microarray includes 111 examples of data categories, and that the target molecule data may include a name of the probe (paragraph 123), clone ID (paragraph 134), Unigene cluster ID, gene symbol, locus ID, chromosome ID, GenBank accession number, tissue from which the sample applied to the probe was extracted, gene map, gene name, organism from which the sample was extracted, and sequence of the probe, (paragraphs 135-114).

Taylor does not show a memory element that contains data of the microarray features. Taylor does not show data concerning molecules whose synthesis is directed by the molecule

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that binds to a probe in the microarray. Taylor does not show headers that are associated with the microarray features.

Nova et al. shows in the abstract an array comprising a memory comprising data. In columns 6 and 8 Nova et al. shows that the array memory may comprise data of the nucleic acids in the array. In columns 6 and 8 Nova et al. shows that the array data comprise identifying information. In figure 43 and column 74, Nova et al. shows data of an array that comprises headers and data for three types of data of the array. In column 16, lines 43-45 show that identification codes are associated with elements of the array. In column 50, lines 26-29, Nova et al. shows that identification codes can be associated with an array. In column 54, lines 37-50, and column 72, lines 35-45, Nova et al. shows that identification codes of arrays in the logic apparatus are used as links to the data of the array. In column 13, Nova et al. shows that the memory may contain data of molecules that are synthesized by the array. In columns 13-14 Nova et al. shows that arrays with memory are useful to track or identify molecules that interact with the array in various types of assays.

Ramdas et al. shows three systems that allow for automated analysis of microarrays that comprise scanners and computer controlled visualization systems in the abstract and throughout. Ramdas et al. conclude on page 552 that all three systems provide useful and comparable outputs of data from a microarray.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the oligonucleotide arrays of Lockhart et al. to assess gene expression levels by use of the virtual array of Taylor because Taylor shows a method of analyzing the data obtained from a microarray. It would have been further obvious to use the array with memory of

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Nova et al. because Nova et al. shows that their array with memory is useful to track or identify molecules that interact with an array. It would have been further obvious to include instructions in the memory of the array to use subsets of the array because Taylor shows instances in which only a portion of the data is of interest and recording instructions to use portions of an array for different purposes would allow the virtual array of Taylor to select the data of the array that is of interest. It would have been further obvious to associate headers such as identification codes with array data because Nova et al. provides guidance to do so for the purpose of accessing data of a microarray of interest. Regarding the limitations of claim 5 that the data include molecular function, biological process, and cellular component of the target molecule to which the probe hybridizes, such data inherently includes the molecular function and the biological process relevant to the target molecule in the name of the gene, and Lockhart et al. shows that mRNA can be isolated from the cytoplasmic compartment of cells. Regarding the feature extraction step of claim 1, the use of a portion of the data as suggested by Taylor extracts features from the microarray for further analysis. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add to the system any of the scanners of Ramdas et al. because Ramdas et al. shows that the scanners allow for automation and useful determinations of the data in a microarray.

8. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above, and further in view of Agilent G2565AA Microarray Scanner System User Manual (May 2002).

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The claims are drawn to a virtualizing microarray system comprising a microarray comprising a memory element that contains data of the microarray features and instructions that generate data of a subset of the data of the microarray features. In addition to the microarray the system comprises a processing component that processes a subset of the features of the microarray at a scanning step.

Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above shows processing a subset of microarray features but does not show processing a subset of microarray features at a scanning step.

Agilent G2565AA Microarray Scanner System User Manual shows on pages 47 and 52-59 that the disclosed scanner apparatus has user adjustable scan regions.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the scan region to include only a subset of features of interest when scanning a microarray because Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above provides guidance to analyze a subset of features of a microarray and Agilent G2565AA Microarray Scanner System User Manual shows a microarray scanner with a user adjustable scan region. The rationale would be to reduce scan time and to reduce the amount of data in later data processing steps.

9. Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above, and further in view of Tseng et al.

The claims are drawn to a virtualizing microarray system comprising a microarray comprising a memory element that contains data of the microarray features and instructions that

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generate data of a subset of the data of the microarray features. In addition to the microarray the system comprises a processing component that processes a subset of the features of the microarray at a feature normalization step.

Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above shows processing a subset of microarray features but does not show processing a subset of microarray features at a feature normalization step.

Tseng et al. shows methods of processing microarray data, including a first filter of data by a quality filter on pages 2550-2552 followed by a normalization of data of ratios of dye intensities that includes use of unregulated housekeeping genes on pages 2552-2554. Tseng et al. shows that normalization allows for comparison of different microarrays from different experiments.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to process a subset of features of interest with a normalization step because Lockhart et al. in view of Taylor in view of Nova et al. in view of Ramdas et al. as applied to claims 1-7, 9, 10, 12, and 14 above provides guidance to analyze a subset of features of a microarray and Tseng et al. shows that normalization of a subset of data that passes an initial quality test allows for comparison of different microarrays from different experiments.

Response to Arguments

10. Applicant's arguments filed 30 January 2009 have been fully considered but they are not persuasive. The applicants state that Taylor fails to show a subset of data from a single microarray, however Taylor shows using a portion of the data of a single microarray at least in paragraphs 28, 29, and 34. The applicants point to paragraph 18 and figure 5 of Taylor to support

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the contention that Taylor shows virtual microarrays must be derived from multiple microarrays. However the cited passages do not state that virtual microarrays must be created from a plurality of microarrays.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/
Primary Examiner, Art Unit 1631